Title 22, California Code of Regulations

ARTICLE 7. NO SIGNIFICANT RISK LEVELS

§ 12701. General.

- (a) The determination of whether a level of exposure to a chemical known to the state to cause cancer poses no significant risk for purposes of Section 25249.10(c) of the Act shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical as known to the state to cause cancer. Nothing in this article shall preclude a person from using evidence, standards, risk assessment methodologies, principles, assumptions or levels not described in this article to establish that a level of exposure to a listed chemical poses no significant risk.
- (b) A level of exposure to a listed chemical, assuming daily exposure at that level, shall be deemed to pose no significant risk provided that the level is determined:
- (1) By means of a quantitative risk assessment that meets the standards described in Section 12703;
 - (2) By application of Section 12707 (Routes of Exposure); or
 - (3) By one of the following, as applicable:
- (A) If a specific regulatory level has been established for the chemical in question in Section 12705, by application of that level.
- (B) If no specific level is established for the chemical in question in Section 12705, by application of Section 12709 (Exposure to Trace Elements) or 12711 (Levels Based on State or Federal Standards) unless otherwise provided.
- (c) The chemicals, routes of exposure and conditions of use specifically listed in this article do not include all chemicals, routes of exposure and conditions of use that pose no significant risk. The fact that a chemical, route of exposure or condition of use does not appear in this article does not mean that it poses a significant risk.
- (d) This article establishes exposure levels posing no significant risk solely for purposes of Section 25249.10(c) of the Act. Nothing in this article shall be construed to establish exposure or risk levels for other regulatory purposes.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

§ 12703. Quantitative Risk Assessment.

- (a) A quantitative risk assessment which conforms to this section shall be deemed to determine the level of exposure to a listed chemical which, assuming daily exposure at that level, poses no significant risk. The assessment shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for listing the chemical as known to the state to cause cancer. In the absence of principles or assumptions scientifically more appropriate, based upon the available data, the following default principles and assumptions shall apply in any such assessment:
- (1) Animal bioassay studies for quantitative risk assessment shall meet generally accepted scientific principles, including the thoroughness of experimental protocol, the degree to which dosing resembles the expected manner of human exposure, the temporal exposure pattern, the duration of study, the purity of test material, the number and size of exposed groups, the route of exposure, and the extent of tumor occurrence.
- (2) The quality and suitability of available epidemiologic data shall be appraised to determine whether the study is appropriate as the basis of a quantitative risk assessment, considering such factors as the selection of the exposed and reference groups, reliable ascertainment of exposure, and completeness of follow-up. Biases and confounding factors shall be identified and quantified.
- (3) Risk analysis shall be based on the most sensitive study deemed to be of sufficient quality.
- (4) The results obtained for the most sensitive study deemed to be of sufficient quality shall be applicable to all routes of exposure for which the results are relevant.
- (5) The absence of a carcinogenic threshold dose shall be assumed and nothreshold models shall be utilized. A linearized multistage model for extrapolation from high to low doses, with the upper 95 percent confidence limit of the linear term expressing the upper bound of potency shall be utilized. Time-to-tumor models may be appropriate where data are available on the time of appearance of individual tumors, and particularly when survival is poor due to competing toxicity.
- (6) Human cancer potency shall be derived from data on human or animal cancer potency. Potency shall be expressed in reciprocal milligrams of chemical per kilogram of bodyweight per day. Interspecies conversion of animal cancer potency to human cancer potency shall be determined by multiplying by a surface area scaling factor equivalent to the ratio of human to animal bodyweight, taken to the one-third power. This is equivalent to a scaling factor of 14 when extrapolating from mouse data and a scaling factor of 6.5 when extrapolating from rat data.

- (7) When available data are of such quality that physiologic, pharmacokinetic and metabolic considerations can be taken into account with confidence, they may be used in the risk assessment for inter-species, inter-dose, and inter-route extrapolations.
- (8) When the cancer risk applies to the general population, human body weight of 70 kilograms shall be assumed. When the cancer risk applies to a certain subpopulation, the following assumptions shall be made, as appropriate:

Kilograms of Body Weight
70
58
58
40
20
10

- (b) For chemicals assessed in accordance with this section, the risk level which represents no significant risk shall be one which is calculated to result in one excess case of cancer in an exposed population of 100,000, assuming lifetime exposure at the level in question, except where sound considerations of public health support an alternative level, as, for example:
- (1) where chemicals in food are produced by cooking necessary to render the food palatable or to avoid microbiological contamination; or
- (2) when chlorine disinfection in compliance with all applicable state and federal safety standards is necessary to comply with sanitation requirements; or
- (3) where a clean-up and resulting discharge is ordered and supervised by an appropriate governmental agency or court of competent jurisdiction.

§ 12705. Specific Regulatory Levels Posing No Significant Risk.

- (a) Daily exposure to a chemical at a level which does not exceed the level set forth in subsections (b), (c) and (d) for such chemical shall be deemed to pose no significant risk within the meaning of Section 25249.10(c) of the Act.
- (b) Levels of exposure deemed to pose no significant risk may be determined by the lead agency based on a risk assessment conducted by the lead agency pursuant to the guidelines set forth in Section 12703, or a risk assessment reviewed by the lead agency and determined to be consistent with the guidelines set forth in Section 12703.

(1) The following levels based on risk assessments conducted or reviewed by the lead agency shall be deemed to pose no significant risk:

Chemical Name	Level (micrograms/day)
Acrylonitrile	0.7
Aldrin	0.04
Arsenic	0.06 (inhalation)
Asbestos	100 fibers inhaled/day*
Benzene	7
Benzidine	0.001
Benzofuran	1.1
Bis(2-chloroethyl)ether	0.3
Bis(chloromethyl)ether	0.02
Butylated hydroxyanisole	4000
Cadmium	0.05 (inhalation)
Carbon tetrachloride	5
N-Carboxymethyl-N-nitrosourea	0.70
Chloroethane	150
Chromium (hexavalent compounds)	0.001 (inhalation)
DDT, DDE and DDD (in combination)	2
1,2-Dibromo-3-chloropropane (DBCP)	0.1
para-Dichlorobenzene	20
3,3'-Dichlorobenzidine	0.6
Dichloromethane (Methylene chloride)	200 (inhalation)
Dieldrin	0.04
Di(2-ethylhexyl)phthalate (DEHP)	310
3,3'-Dimethoxybenzidine	0.15
3,3'-Dimethoxybenzidine dihydrochloride	0.19
3,3'-Dimethylbenzidine	0.044
3,3'-Dimethylbenzidine dihydrochloride	0.059
1,4-Dioxane	30
Epichlorohydrin	9
Ethylene dibromide	0.2 (ingestion)
	3 (inhalation)
Ethylene dichloride	10
Ethylene oxide	2
Hexachlorobenzene	0.4
Hexachlorodibenzodioxin	0.0002

Hexachlorocyclohexane (technical grade)	0.2
Lead	15 (oral)
Lead acetate	23 (oral)
Lead phosphate	58 (oral)
Lead subacetate	41 (oral)
Lead Subacciate	41 (Olul)
2-Methylaziridine (propyleneimine)	0.028
Methylhydrazine	0.058 (oral)
	0.090 (inhalation)
Methylhydrazine sulfate	0.18
5-Morpholinomethyl-3-[(5-nitrofurfurylidene)	0.18
-amino]-2-oxazolidinone	
MX (3-chloro-4-(dichloromethyl)-5-hydroxy-2(5H)-fura	none) 0.11
N-Nitroso-n-dibutylamine	0.06
N-Nitrosodiethylamine	0.02
N-Nitrosodimethylamine	0.04
N-Nitrosodiphenylamine	80
N-Nitrosodi-n-propylamine	0.1
N-Nitroso-N-ethylurea	0.03
N-Nitroso-N-methylurea	0.006
Phenyl glycidyl ether	5.0
Phenylhydrazine	1.0
Phenylhydrazine hydrochloride	1.4
Polybrominated biphenyls	0.02
Polygeenan	1200
2,3,7,8-Tetrachlorodibenzo-p-dioxin	0.000005
Tetranitromethane	0.059
Toxaphene	0.6
Trichloroethylene	50 (ingestion)
•	80 (inhalation)
2,4,6-Trichlorophenol	10
Urethane	0.7
Vinyl chloride	3
2,6-Xylidine	110

^{*}Fibers equal to or greater than 5 micrometers in length and 0.3 micrometers in width, with a length to width radio of greater than or equal to 3:1 as measured by phase contrast microscopy.

- (2) Whenever the lead agency proposes to formally adopt, pursuant to this subsection, a level which shall be deemed to pose no significant risk of cancer, assuming daily exposure at that level, the lead agency shall provide to each member of the Carcinogen Identification Committee notice of the proposed action, a copy of the proposed level, and a copy of the initial statement of reasons supporting the proposal. The close of the public comment period for any such proposal shall be scheduled by the lead agency so as to permit the Carcinogen Identification Committee the opportunity to review such proposal and provide comment to the lead agency. Any such comment by the Carcinogen Identification Committee shall become a part of the formal rulemaking file. Nothing in this subsection shall be construed to prevent members of the Carcinogen Identification Committee from providing comments individually on any such proposal, or to require the Carcinogen Identification Committee to submit any comment.
- (c) Unless a specific regulatory level for a chemical known to the state to cause cancer has been established in subsection (b), levels of exposure deemed to pose no significant risk may be determined by the lead agency based on state or federal risk assessments.
- (1) Any interested party may request the lead agency to reevaluate a level established in this subsection based on scientific considerations that indicate the need for the lead agency to develop its own risk assessment or to conduct a detailed review of the risk assessment used to derive the level in question. Such request shall be made in writing, and shall include a description of the scientific considerations that indicate the need for the lead agency to develop its own risk assessment or to conduct a detailed review of the risk assessment used to derive the level in question. The lead agency may establish a level for the chemical in question in subsection (b) as it deems necessary.
- (2) The following levels based on state or federal risk assessments shall be deemed to pose no significant risk:

Chemical Name

Chemical Name	Level (micrograms/day)	
Acetaldehyde	90 (inhalation)	
Acrylamide	0.2	
Aniline	100	
Azobenzene	6	
Benzo[a]pyrene	0.06	
Benzyl chloride	4	
Beryllium oxide	0.1	
Beryllium sulfate	0.0002	
Bromodichloromethane	5	
1,3-Butadiene	0.4	
Chlordane	0.5	
Chloroform	20 (ingestion)	

Coke oven emissions	40 (inhalation) 0.3
DDVP (Dichlorvos) Dichloromethane (Methylene chloride) 2,4-Dinitrotoluene	2 50 2
Folpet Formaldehyde (gas) Furmecyclox	200 40 20
Heptachlor Heptachlor epoxide	0.2 0.08
Hexachlorocyclohexane alpha isomer beta isomer gamma isomer	0.3 0.5 0.6
Hydrazine Hydrazine sulfate	0.04 0.2
4,4'-Methylene bis(N,N-dimethyl)benzeneamine	20
Nickel refinery dust Nickel subsulfide N-Nitrosodiethanolamine N-Nitrosomethylethylamine N-Nitrosopyrrolidine	0.8 0.4 0.3 0.03 0.3
Pentachlorophenol Polychlorinated biphenyls (PCBs)	40 0.09
Tetrachloroethylene	14

- (d) Unless a specific regulatory level has been established for a chemical known to the state to cause cancer in subsection (b) or (c), levels of exposure deemed to pose no significant may be determined by the lead agency using an expedited method consistent with the procedures specified in Section 12703.
- (1) An interested party may request the lead agency to reevaluate a level established in this subsection and to consider the adoption, in subsection (c), of a level based on a state or federal risk assessment. Such request shall be made in writing, and shall include a copy of the state or federal risk assessment which the interested party wishes the lead agency to consider as the basis for a level in subsection (c). The lead agency may establish a level in subsection (c) for the chemical in question based on a state or federal risk assessment as it deems necessary.

- (2) An interested party may request the lead agency to reevaluate a level established in this subsection based on scientific considerations that indicate the need for a conventional risk assessment. Such request shall be made in writing, and shall include a description of the scientific considerations that indicate the need for a conventional risk assessment. The lead agency may conduct a conventional risk assessment for the chemical in question, and establish a level in subsection (b) as it deems necessary.
- (3) The following levels of exposure based on risk assessments conducted by the lead agency using an expedited method consistent with the procedures specified in Section 12703 shall be deemed to pose no significant risk:

Chemical Name

	zever (imierograms/day)
A-alpha-C (2-Amino-9H-pyridol[2,3-b]indole)	2
Acetamide	10
2-Acetylaminofluorene	0.2
Actinomycin D	0.00008
AF-2;[2-(2-furyl)-3(5-nitro-2-furyl)acrylamide]	3
2-Aminoanthraquinone	20
o-Aminoazotoluene	0.2
4-Aminobiphenyl (4-aminodiphenyl)	0.03
3-Amino-9-ethylcarbazole hydrochloride	9
1-Amino-2-methylanthraquinone	5
2-Amino-5-(5-nitro-2-furyl)-1,3,4-thiadiazole	0.04
Amitrole	0.7
o-Anisidine	5
<i>o</i> -Anisidine hydrochloride	7
Aramite	20
Auramine	0.8
Azaserine	0.06
Azathioprine	0.4
Benzyl violet 4B	30
beta-Butyrolactone	0.7
Carbazole	4.1
Captafol	5
Captan	300
Chlorambucil	0.002
Chlordecone (Kepone)	0.04
Chlorendic acid	8
Chlorinated paraffins (Average chain length, C12;	
approximately 60 percent chlorine by weight)	8
Chloromethyl methyl ether (technical grade)	0.3
3-Chloro-2-methylpropene	5
4-Chloro-ortho-phenylenediamine	40

Level (micrograms/day)

Chlorothalonil p-Chloro-o-toluidine p-Chloro-o-toluidine hydrochloride Chlorozotocin C.I. Basic Red 9 monohydrochloride Cinnamyl anthranilate p-Cresidine Cupferron Cyclophosphamide (anhydrous) Cyclophosphamide (hydrated)	200 3 3.3 0.003 3 200 5 3 1
D&C Red No. 9	100
Dacarbazine	0.01
Daminozide Daminozide	40
Dantron (Chrysazin;1,8-Dihydroxyanthraquinone)	9
2,4-Diaminoanisole	30
2,4-Diaminoanisole sulfate	50
4,4'-Diaminodiphenyl ether (4,4'-Oxydianiline)	5
2,4-Diaminotoluene	0.2
Dibenz[a,h]anthracene	0.2
1,1-Dichloroethane	100
Diethylstilbestrol	0.002
Diglycidyl resorcinol ether (DGRE)	0.4
Dihydrosafrole	20
4-Dimethylaminoazobenzene	0.2
trans-2[(Dimethylamino)methyliminol]-5-[2-(5-nitro-	
2-furyl)vinyl]-1,3,4-oxadiazole	2
7,12-Dimethybenz(a)anthracene	0.003
Dimethylcarbamyl chloride	0.05
1,2-Dimethylhydrazine	0.001
Dimethylvinylchloride	20
Direct Black 38 (technical grade)	0.09
Direct Blue 6 (technical grade)	0.09
Direct Brown 95 (technical grade)	0.1
Disperse Blue 1	200
Estradiol 17B	0.02
Ethyl-4,4'-dichlorobenzilate (chlorobenzilate)	7
Ethylene thiourea	20
Ethyleneimine	0.01
2-(2-Formylhydrazino)-4-(5-nitro-2-furyl)thiazole	0.3
Glu-P-1 (2-Amino-6-methyldipyrido[1,2-a:3',2'-d]imidazole	0.1
Glu-P-2 (2-Aminodipyrido[1,2-a:3',2'-d]imidazole	0.1
Gyromitrin (Acetaldehyde methylformylhydrazone)	0.07
Syronnam (ricomidenty de memy normy my drazone)	0.07

HC Blue 1 Hexachloroethane Hydrazobenzene (1,2-Diphenylhydrazine)	10 20 0.8
IQ (2-Amino-3-methylimidazo[4,5-f]quinoline) Isobutyl nitrite	0.5 7.4
Lasiocarpine	0.09
Me-A-alpha-C (2-Amino-3-methyl-9H-pyrido[2,3-b]indole) MeIQ (2-Amino-3,4-dimethylimidazo[4,5-f] quinoline) MeIQx (2-Amino-3,8-dimethylimidazo[4,5-f] quinoxaline) Melphalan Methyl carbamate 3-Methylcholanthrene 4,4'-Methylene bis(2-chloraniline) 4,4'-Methylene bis(2-methylaniline) 4,4'-Methylenedianiline 4,4'-Methylenedianiline dihydrochloride Methyl methanesulfonate 2-Methyl-1-nitroanthraquinone (of uncertain purity) N-Methyl-N'-nitro-N-nitrosoguanidine Methylthiouracil Michler's ketone Mirex Mitomycin C	0.6 0.46 0.41 0.005 160 0.03 0.5 0.8 0.4 0.6 7 0.2 0.08 2 0.8 0.04 0.09
Monocrotaline	0.07
Nalidixic acid 2-Naphthylamine Nitrilotriacetic acid Nitrolotriacetic acid, trisodium salt monohydrate 5-Nitroacenaphthene 5-Nitro-o-anisidine Nitrofen (technical grade) Nitrofurazone 1-[(5-Nitrofurfurylidine)-amino]-2-imidazolidinone N-[4-(5-Nitro-2-furyl)-2-thiazolyl]acetamide p-Nitrosodiphenylamine 4-(N-Nitrosomethylamino)-1-(3-pyridyl)-1-butanone N-Nitrosonorpholine N-Nitrosonornicotine N-Nitrosonornicotine	28 0.4 100 70 6 10 9 0.5 0.4 0.5 30 0.014 0.006 0.1 0.5 0.07
Phenacetin	300

Phenazopyridine Phenazopyridine hydrochloride Phenesterin Phenobarbital Phenoxybenzamine Phenoxybenzamine hydrochloride o-Phenylenediamine o-Phenylenediamine dihydrochloride o-Phenylphenate sodium Ponceau MC (D&C Red No. 5) Ponceau 3R (FD&C Red No. 1) Potassium bromate Procarbazine Procarbazine Procarbazine hydrochloride 1,3-Propane sultone beta-Propiolactone Propylthiouracil Reserpine	4 5 0.005 2 0.2 0.3 26 44 200 200 40 1 0.05 0.06 0.3 0.05 0.7
Safrole Sterigmatocystin Streptozotocin Styrene oxide Sulfallate	3 0.02 0.006 4 4
1,1,2,2-Tetrachloroethane Thioacetamide 4,4'-Thiodianiline Thiourea Toluene diisocyanate o-Toluidine o-Toluidine hydrochloride Trimethyl phosphate Tris(1-aziridinyl)phosphine sulfide (Thiotepa) Tris(2,3-dibromopropyl)phosphate Trp-P-1 (Tryptophan-P-1) Trp-P-2 (Tryptophan-P-2)	3 0.1 0.05 10 20 4 5 24 0.06 0.3 0.03 0.2
Vinyl trichloride (1,1,2-Trichloroethane)	10

§ 12707. Route of Exposure.

- (a) Where scientifically valid absorption studies conducted according to generally accepted standards demonstrate that absorption of a chemical through a specific route of exposure can be reasonably anticipated to present no significant risk of cancer at levels of exposure not in excess of current regulatory levels, the lead agency may identify the chemical as presenting no significant risk by that route of exposure. Any exposure, discharge or release of a chemical so identified shall be deemed to present no significant risk to the extent that it results in exposure to humans by the identified route, and does not exceed the level established in any other applicable federal or state standard, regulation, guideline, action level, license, permit, condition, requirement or order.
- (b) The following chemicals present no significant risk of cancer by the route of ingestion:
 - (1) Asbestos
 - (2) Beryllium and beryllium compounds
 - (3) Cadmium and cadmium compounds
 - (4) Chromium (hexavalent compounds)
 - (5) Nickel and nickel compounds

§ 12709. Exposure to Trace Elements.

- (a) Except where a specific regulatory level is established in Section 12705, exposure to a trace element listed in subsection (b) shall be deemed to pose no significant cancer risk so long as the reasonably anticipated level of exposure to the chemical does not exceed the level set forth in subsection (b).
- (b) Element No Significant Risk Level in micrograms per day

Arsenic (inorganic) 10 (except inhalation)
Beryllium 0.1

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

§ 12711. Levels Based on State or Federal Standards.

- (a) Except as otherwise provided in Section 12705, 12707, or 12709, levels of exposure deemed to pose no significant risk may be determined as follows:
- (1) Where a state or federal agency has developed a regulatory level for a chemical known to the state to cause cancer which is calculated to result in not more than

one excess case of cancer in an exposed population of 100,000, such level constitute the no significant risk level.

- (2) For drinking water, the following levels shall be deemed to pose no significant risk:
- (A) Drinking water maximum contaminant levels adopted by the Department of Health Services for chemicals known to the state to cause cancer;
- (B) Drinking water action levels for chemicals known to the state to cause cancer for which maximum contaminant levels have not been adopted;
- (C) Specific numeric levels of concentration for chemicals known to the state to cause cancer which are permitted to be discharged or released into sources of drinking water by a Regional Water Quality Control Board in a water quality control plan or in waste discharge requirements, when such levels are based on considerations of minimizing carcinogenic risks associated with such discharge or release.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

§ 12713. Exposure to Food, Drugs, Cosmetics and Medical Devices. Section Repealed.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

§ 12721. Level of Exposure to Chemicals Causing Cancer.

- (a) For the purposes of the Act, "level in question" means the chemical concentration of a listed chemical for the exposure in question. The exposure in question includes the exposure for which the person in the course of doing business is responsible and does not include exposure to a listed chemical from any other source or product.
- (b) For purposes of the Act, "lifetime exposure" means the reasonably anticipated rate of exposure for an individual to a given medium of exposure measured over a lifetime of seventy years.
- (c) For purposes of Section 25249.10(c) of the Act, the level of exposure to a chemical listed as causing cancer, assuming lifetime exposure at the level in question, shall be determined by multiplying the level in question (stated in terms of a concentration of a chemical in a given medium) times the reasonably anticipated rate of exposure for an individual to the given medium of exposure measured over a lifetime of seventy years.

- (d) The following assumptions shall be used to calculate the reasonably anticipated rate of exposure to a chemical listed as causing cancer, unless more specific and scientifically appropriate data are available:
- (1) For an exposure reasonably expected to affect the general population in any geographic area:
 - (A) The exposed individual ingests two litters of drinking water per day.
 - (B) The exposed individual inhales twenty cubic meters of air per day.
 - (C) The exposed individual has a lifespan of seventy years.
- (2) For an exposure reasonably anticipated to affect a certain subpopulation of the general population in any geographic area, specific data (if available) relating to that subpopulation shall be used to determine the level of exposure.
- (A) In the absence of more specific and scientifically appropriate data, the following assumptions should be made as appropriate:

Subpopulation	Water liters/day	Air cubic meters/day
Man (18+ years of age)	2	20
Woman (18 + years of age)	2	20
Woman with conceptus	2	20
Adolescent (10-18 years of age)	2	20
Child (2-10 years of age)	2	15
Infant (0-2 years of age)	1	4

- (B) For an exposure reasonably expected to affect the conceptus (embryo or fetus), the gestation period for the exposed conceptus is nine months.
- (3) For workplace exposures, the exposed worker inhales ten cubic meters of workplace air per eight-hour day, forty hours per week, fifty weeks per year over a forty-year period. The exposed individual from the general population who occasionally enters a workplace inhales 1.25 cubic meters of workplace air for one hour per month for a seventy-year lifetime.
- (4) For exposures to consumer products, lifetime exposure shall be calculated using the average rate of intake or exposure for average users of the consumer product, and not on a per capita basis for the general population. The average rate of intake or exposure shall be based on data for use on a general category or categories of consumer products, such as the United States Department of Agriculture Home Economic Research Report, Foods Commonly Eaten by Individuals: Amount Per Day and Per Eating Occasion, where such data are available.